5. 510(K) SUMMARY

Submitter's Name:	Spinal USA, Inc.
Submitter's Address:	2050 Executive Drive Pearl, MS 39208
Submitter's Telephone:	601-420-4244
Contact Person:	Meredith L. May, MS Empirical Testing Corp. 719.337.7579
Date Summary was Prepared:	28 June 2013
Trade or Proprietary Name:	Vault-C Standalone Cervical Interbody Fusion System
Common or Usual Name:	Intervertebral body fusion device.
Classification:	Class II per 21 CFR §888.3080
Product Code:	OVE
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Predicate Devices:	Centinel Spine Stalif C System (K120819) Biomet Spine, Solitaire-C System (K113796) LDR Spine ROI-C (K091088, K113559) Life Spine, Inc. Pro-Link Stand-Alone Cervical System (K121151) Globus Medical, Inc COALITION Spacer (K083389)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Vault-C consists of a spacer assembly including a PEEK cage with a titanium alloy plate and titanium bone screws for intervertebral body fusion. Screws are available in a variety of diameter-length combinations. The titanium and PEEK spacers are available in a variety of depths, widths and heights. Fixation is achieved by inserting bone screws through the openings in the spacer into the vertebral bodies of the cervical spine.

INDICATIONS FOR USE

The Vault-C Standalone Cervical Interbody Fusion System is a standalone cervical interbody device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3-T1) at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The Vault-C implants are used with two titanium alloy screws and filled with autogenous bone graft material to facilitate fusion in the cervical spine. The device is placed via an anterior approach at the C-3 to T-1 disc levels.

Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral fusion device.

The indication for use for the Spinal USA Vault-C is similar to that of the Centinel Spine Stalif C System (K120819), Biomet Spine Solitaire-C System (K113796), LDR Spine ROI-C (K091088, K113559), Life Spine, Inc. Pro-Link Stand-Alone Cervical System (K121151) and Globus Medical, Inc. COALITION Spacer (K083389).

TECHNICAL CHARACTERISTICS

The spacers are manufactured from PEEK-OPTIMA® (ASTM F2026), titanium alloy (ASTM F136), and tantalum (ASTM F560-05). The predicate devices are manufactured from the same or similar materials. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism

PERFORMANCE DATA

The Vault-C has been tested in the following test modes:

- Static Axial Compression (ASTM F-2077)
- Static Compression-Shear (ASTM F-2077)
- Static Torsion (ASTM F-2077)
- Dynamic Axial Compression (ASTM F-2077)
- Dynamic Compression-Shear (ASTM F-2077)
- Dynamic Torsion (ASTM F-2077)
- Subsidence (ASTM F-2267 and ASTM F-2077)

The results of this non-clinical testing show that the strength of the Vault-C is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Vault-C is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 25, 2013

Spinal USA
% Ms. Meredith May
Partnership Manager
Empirical Testing Corporation
4628 Northpark Drve
Colorado Springs, Colorado 80918

Re: K132029
Trade/Device Name: Vault-C Standalone Cervical Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: October 8, 2013
Received: October 18, 2013

Dear Ms. May:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132029

Device Name
Vault-C Standalone Cervical Interbody Fusion System

Indications for Use *(Describe)*

The Vault-C Standalone Cervical Interbody Fusion System is a standalone cervical interbody device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3-T1) at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The Vault-C implants are used with two titanium alloy screws and filled with autogenous bone graft material to facilitate fusion in the cervical spine. The device is placed via an anterior approach at the C-3 to T-1 disc levels. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral fusion device

Type of Use (Select one or both, as applicable)
☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD
Division of Orthopedic Devices